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The Clinical Research Alliance at UNC

WWW.MED.UNC.EDU/UNCCRA



Dr. David Peden
Director & Chief
Research Officer

Michael Sledge
Vice President &
Chief Business Officer



School of Medicine



SCHOOL OF MEDICINE
Clinical Research Alliance

UNC Clinical Research

History of Clinical Research in NC

The history of clinical research in North Carolina reflects a progression from early lessons in safety and ethics to global leadership in innovation.

UNC was among the early institutions advancing clinical research in the state, developing academic expertise alongside peer institutions and helping establish the foundation for North Carolina's research ecosystem.

Faculty and alumni founded PPD, Quintiles (now IQVIA) and Rho, extending academic expertise into the global research industry and positioning North Carolina as a leader in clinical innovation.

Today, UNC's School of Medicine and the Clinical Research Alliance carry this legacy forward by supporting and enabling clinical research across a broad range of therapeutic areas, including HIV, oncology, pediatrics and rare disease.

Why NC is Ideal for Clinical Research

Large & Growing – 10.8M residents, projected to be the 7th most populous state by the 2030s.

Demographically Representative – Rapid growth in Hispanic, Black, and foreign-born populations enables more representative trials.

Metro + Rural Reach – 40% of residents live in rural areas, giving access to underrepresented patient groups.

High Disease Burden – Above-average rates of cancer, cardiovascular disease, diabetes, and obesity align with the CRA's core focus areas.

Research Ecosystem – RTP hosts 300+ life sciences companies and major Clinical Research Organizations (CROs).

Why Clinical Research Matters

Clinical research in North Carolina has always been about more than research. It is about improving human health at every level.

From rural towns to major medical centers, patients gain access to therapies years before they reach the market. Families are given hope through studies that tackle HIV, oncology, pediatrics, rare diseases, and conditions that once had no treatments at all.

Communities benefit when discoveries made in Chapel Hill, Durham, and across the Research Triangle bring jobs, investment, and pride in being part of something larger.

Most of all, the work done here reflects a people-first partnership with research that ensures North Carolina is not only participating in medical discovery, but helping shape how healthcare advances worldwide.

Organizational Needs

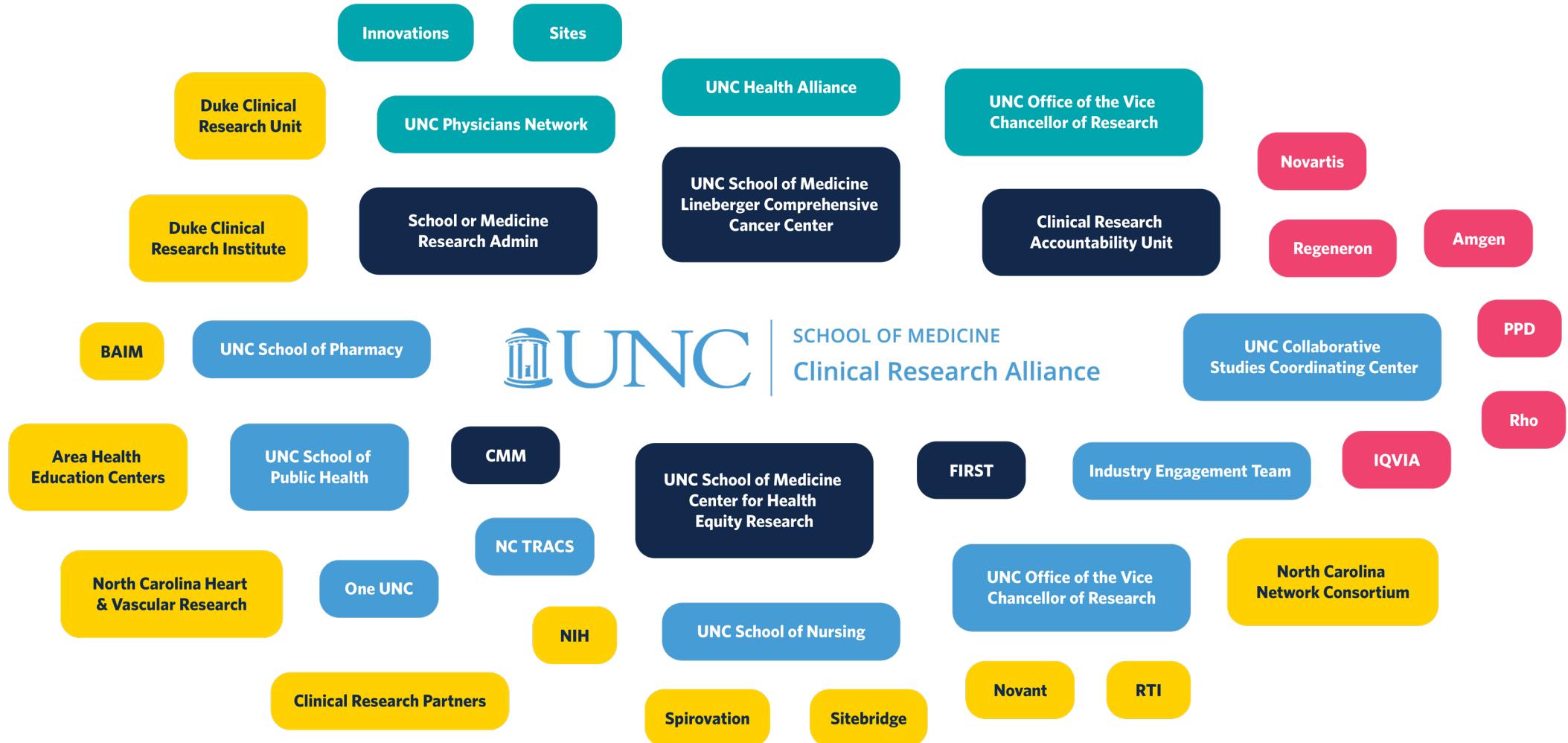
UNC has several units which support clinical research

UNC investigators have traditionally excelled at developing federally funded clinical/ translational research programs

However, there is a need to increase and develop industry funded clinical research as well as maximize federal initiatives

Investigators who lead multi-site clinical trials with national scope will have significant impact in translating discoveries to clinical practice

With these needs in mind, the UNC Clinical Research Alliance was founded to be the School of Medicine unit which supports investigator effort in leading multi-site clinical trials



KEY:

School of Medicine

UNC Health

UNC Chapel Hill

Pharma/CRO

Other

Clinical Research Alliance



UNC | SCHOOL OF MEDICINE
Clinical Research Alliance

Mission & Vision

**Improving Human Health
Together**

Vision

We believe in a world where clinical research moves from question to answer faster, bringing evidence into practice and improving health outcomes for patients in communities across North Carolina and beyond.

Mission

Our Mission is to coordinate rigorous multi-site clinical research that turns discovery into reliable evidence and measurable outcomes, uniting our expertise with investigators, partners, sponsors and communities to raise the standards of medicine and care.

CRA Aspirations

Advance Patient Impact

Provide patients in North Carolina and beyond with access to cutting-edge therapies and clinical trials that improve lives.

Empower Investigators

Offer the resources, infrastructure and support that allow investigators to focus on innovation and discovery.

Strengthen Sponsor Partnerships

Be recognized as the gold standard academic partner by delivering speed, consistency, and scientific excellence.

Lead Nationally

Establish UNC as a national leader where discovery and a patient-first approach converge to define the future of clinical research.

The UNC CRA Advantage

Patients gain earlier access to innovative therapies and interventions, supported by trials designed with equity at their core, ensuring more opportunities for life-changing outcomes.

Investigators are backed by a robust infrastructure that streamlines trial design, compliance, and operations. The CRA fosters collaboration across disciplines, helping ideas move efficiently from concept to clinic.

Sponsors benefit from a single entry point into a leading academic health system with multiple sites. Through coordinated processes, the CRA delivers faster activation, regulatory confidence and trusted scientific leadership.

Industry Overview – Core Trends

Real-world Evidence (RWE): Now central to regulatory approval and post-market monitoring.

Decentralized trials (DCTs): Expanding access and diversity through remote and hybrid models.

Oncology pipeline: Remains the largest and fastest-growing area of global trials.

Investment Hot Spots

- Immunotherapy
- Precision medicine
- Infectious Diseases
- Rare diseases
- Digital health/AI in trials
- Oncology

Industry Overview – Takeaways

The next decade of clinical research will be defined by hybrid trials, biomarker-driven design and AI-enabled operations.

As sponsors invest in oncology, immunotherapy and rare disease research, they need faster activation, regulatory confidence and diverse patient access.

The CRA delivers all three through its unified ecosystem.

Core Values



Driving Discovery

We advance North Carolina's long-standing legacy of clinical research leadership.

As a catalyst for progress, we bring together investigators, patients, and partners to launch studies that improve lives.

Our work improves human health in our state and across the world.



Trusted Collaboration

We earn trust by showing up with humility, consistency, and care.

We listen closely, speak honestly, and work with integrity across every team and every partnership.

This trust is the foundation for every study we launch and every life we aim to improve.

UNC School of Medicine Core Values

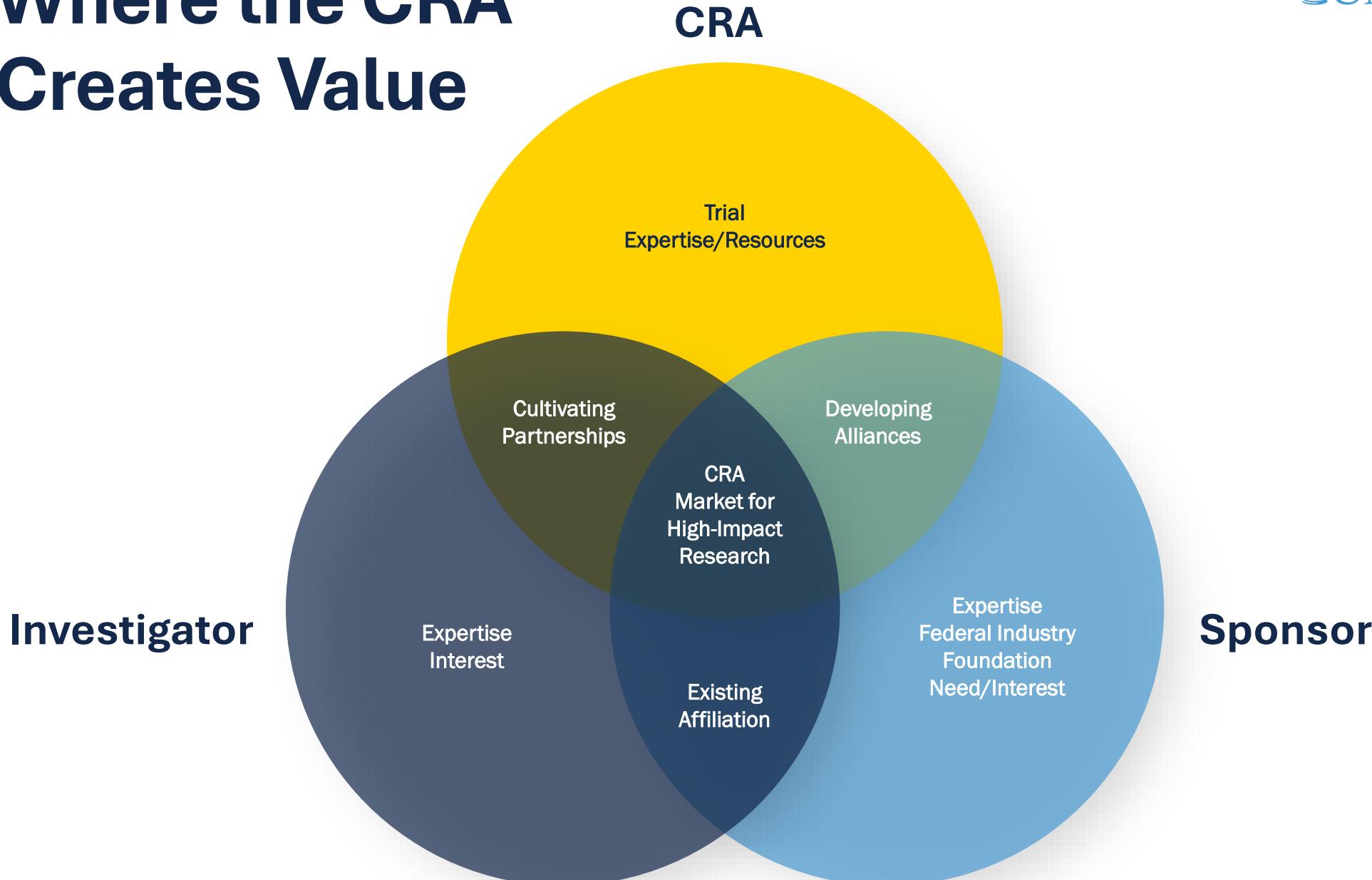
One Great Team

Carolina Care

Leading the Way

It Starts with Me

Where the CRA Creates Value



CRA Leadership



**David Peden,
MD, MS, FAAAAI**
Director & Chief Research Officer

30+ years in research, senior leadership roles at UNC, PI of \$70 million of federal research funding for asthma, 10+ years on FDA Allergenic Products Advisory Committee (6 years as chair) through 2025.



Michael Sledge
VP & Chief Business Officer

20+ years in academic medicine and clinical research with leading AROs and CROs.



Suzanne Kennedy, PhD
Executive Director, Clinical Operations

20+ years in allergy and asthma, 10 years as CRO Research Scientist/co-PI, contributed to observational studies, clinical trials, basic science and translational and implementation research.

CRA Leadership



**Lisa Dusenberry,
MBA**

Senior Director, Business
Development

15+ years of coordinating center award
administration, specializing in
budgeting and proposal management.



**Nasrin H. Babadi,
PhD**

Director, Regulatory and
Compliance

20 years of experience, specializing in
developing regulatory strategies, managing
INDs and IDEs and collaborating with FDA,
academia and industry partners.



**Mac Robinson,
PhD**

Director, Proposal Development
and Scientific Writing

20+ years of research experience,
specializing in grant proposals, trial
documentation and scientific
communications.



**Lara Vaz,
PhD**

Administrative Lead for the
ACTG Leadership and
Operations Center (LOC)

Over 20 years of global experience in HIV
research and clinical trials, with expertise in
IRB leadership, protocol development and
regulatory governance across 40+
countries.

Therapeutic Area Leadership



Joseph J. Eron Jr., MD
[Division of Infectious Diseases](https://www.unc.edu/divisions/medicine/divisions/infectious-diseases/)
(unc.edu)

Infectious Disease



**David Peden,
MD, MS, FAAAAI**
[UNC Clinical Research Alliance](https://www.unc.edu/medicine/cra/)

Asthma | Allergy Immunology &
Respiratory Disease



**Kevin Anstrom, PhD,
MS**
[UNC Gillings School of Global
Public Health](https://www.unc.edu/gillings-school-of-global-public-health/)

Biostatistics & Clinical Trial Design



**Matthew A. Cavender,
MD, MPH, FACC**
[Division of Cardiology](https://www.unc.edu/divisions/medicine/divisions/cardiology/)

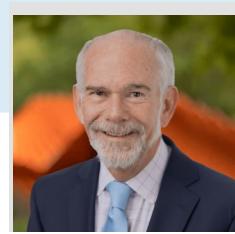
Cardiology

Therapeutic Area Leadership



**Gaurav Dave,
MBBS, DrPH, MPH**
[Abacus \(unc.edu\)](http://Abacus.unc.edu)

Abacus | Center for Thriving
Communities



**John B. Buse,
MD, PhD**
[Division of Endocrinology and
Metabolism \(unc.edu\)](http://DivisionOfEndocrinologyAndMetabolism.unc.edu)

Metabolic Disorders



**Joe Hart III,
PhD ATC**
[UNC Orthopaedics](http://UNCOrthopaedics.unc.edu)

Musculoskeletal



**Zachary Feldman,
MD**
[Department of Psychiatry](http://DepartmentOfPsychiatry.unc.edu)

Psychiatry

CRA Capabilities



Business Services

- Budgeting
- Pre & Post-Award
- Contract Negotiation & Execution
- Agreement Execution (CDA, DUA, Reliance, etc.)
- FDA (IND, IDE, Reports)
- Quality Assurance & Control
- Proposal Management
- Regulatory Strategy
- Science Writing
- Single IRB



Clinical Operations

- DSMB
- Event Review & Adjudication
- Manuscripts, Reports
- Project Leadership
- Protocol Development
- Recruitment & Retention
- Site Management
- Study Communications
- Study Design
- Study Implementation

CRA Site Management

The CRA provides centralized oversight and coordination of clinical trial activity, including access to UNC Health trial sites.

- **Streamlined trial activation**
- **Compliance**
- **Operations management**
- **Assured consistency, quality and efficiency**
- **End-to-End, unified trial management**

CRA Technology

- **Electronic Data Capture (EDC)**
- **Clinical Trials Management Systems (CTMS)**
- **Regulatory (eTMF)**

Finance

The CRA provides comprehensive financial services from strategy to execution in support of clinical trials.

This includes managing budgets, establishing site sub-agreements, optimizing financial processes for large-scale clinical trials with multiple funding sources and strategic financial planning.



Business Development

Our team navigates university systems and industry relationships to prepare compelling proposals, identify clinical sites, and connect with partners. We also assess funding opportunities and coordinate budgets to ensure accurate and timely submissions.

Leader: Lisa Dusenberry, MBA

Senior Director of Business Development



Contracts & Agreements

Trial agreements, sub-contracts and awards in coordination with UNC offices. Our support ensures clarity, speed and fairness in every research partnership.



Clinical Operations

- The CRA oversees day-to-day multi-site operations from staffing and training to data coordination and medical monitoring. This ensures quality, efficiency and consistent delivery across trials.
- Technology/Regulatory Solutions
 - Electronic Data Transfer
 - FDA Part 11 compliance
 - IND/IDE support

Clinical Trial Support

- Primary foci are multi-site Phase 2 and 3 studies
- Phase 1 studies for investigators in supported therapeutic areas or to build relationships with pharma
- CRA also supports multi site federal initiatives

Programs: ACTG

ACTG Leadership Operations Committee (LOC) transition

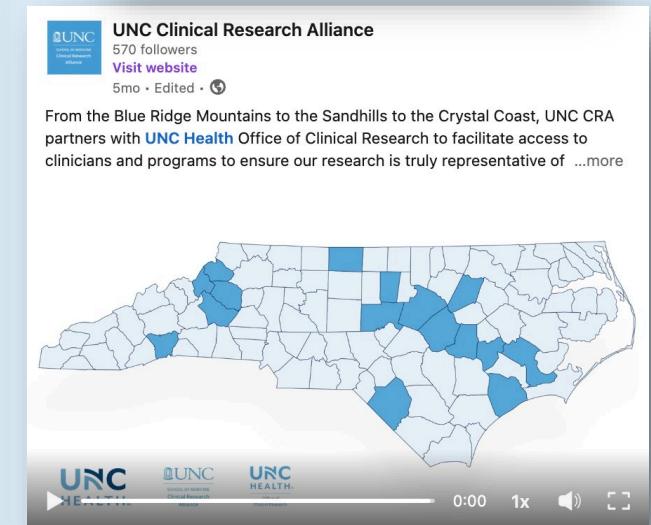
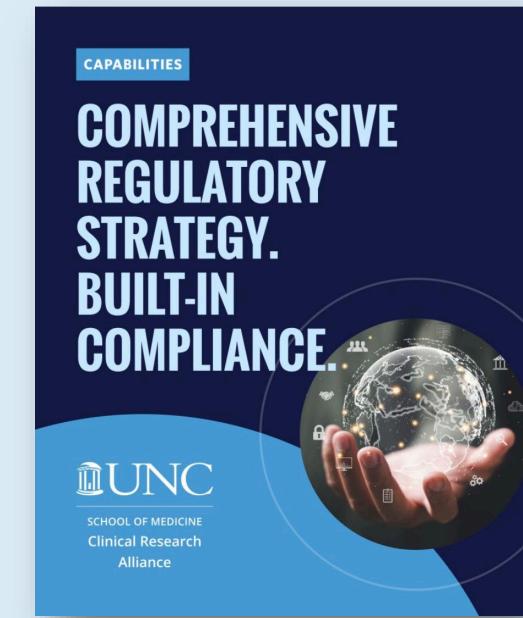
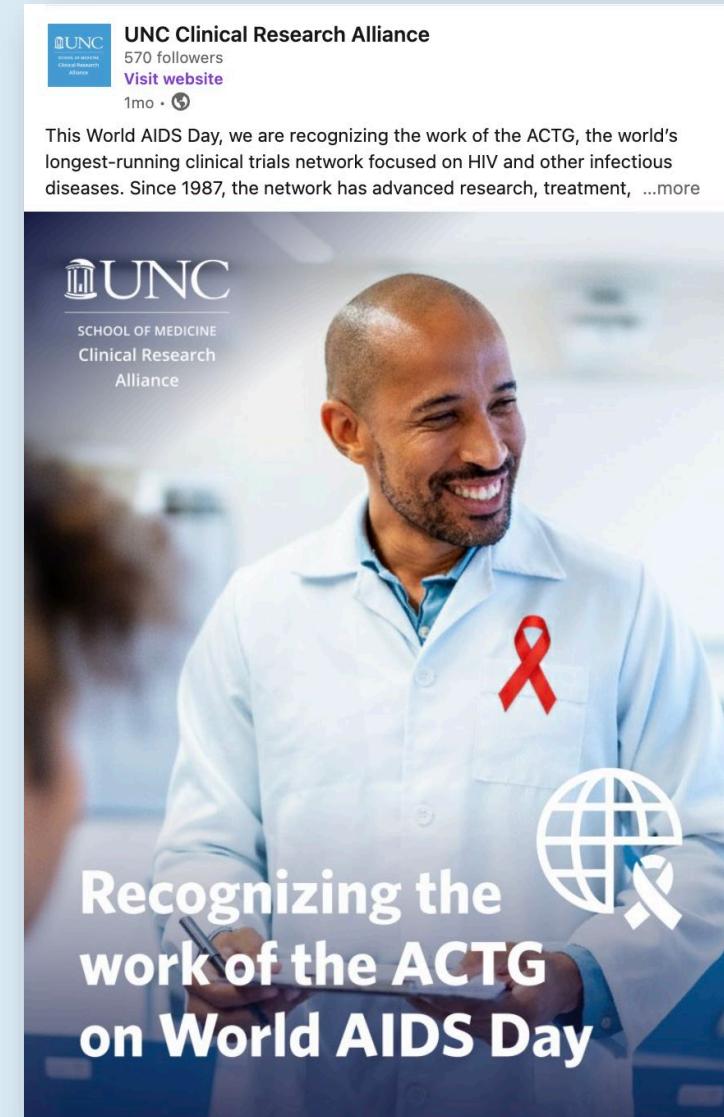
- \$25.1 million Protocol Funds
- \$11.25 million Core Funds

DAIDS Transition Expectations from UNC

- Knowledgeable
- Have vendor, sub agreements, and payment systems in place
- Budget Protocol Funds for personnel and sites
- Have staff in place for project, same resources as UCLA
- Be prepared and able to pivot quickly (eg, next pandemic)

Marketing + Communications

- Over 600+ followers
- Top searchers: pharma, higher ed, hospitals
- Notable orgs: Pfizer, UNC Research, UNC Health Rex
- 40% of followers are senior-level, spanning higher education, health care, research services and biotechnology.



Research Partners

